



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,056	09/20/2001	Mark L. Tykocinski	285332-00002-2	6690

3705 7590 08/15/2003

ECKERT SEAMANS CHERIN & MELLOTT
600 GRANT STREET
44TH FLOOR
PITTSBURGH, PA 15219

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 08/15/2003

uf

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/957,056

Applicant(s)

TYKOCINSKI ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 and 51-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 51-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>13</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The finality of the rejection of the last Office action is withdrawn.

2. Claims 23 and 51-61 are pending.

Claims 24-44, 46, 47, 49 and 50 have been cancelled.

Claims 23 and 51-61 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 37-44, 46, 47, 49 and 50 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cancer vaccine comprising a cell with a first protein (lipidated protein) and second proteins (several fusion proteins) to vaccinate subjects with L5178Y-R and T-50 tumor cells (see Examples 3-5, pages 17-19), does not reasonably provide enablement for the use of a cancer vaccine comprising several cell types in all types of cancer is withdrawn in light of the cancellation of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1642

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 23 and 51-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim and Peacock (Journal of Immunological Methods 158:57-65, 1993/ Document J on IDS) in view of Brunschwig et al. (Journal of Immunology 155:5498-5505, 1995/Document G on IDS). Kim and Peacock (see Materials and methods section) teach a cell having a transferred fusion protein transferred by:

coating the surface of said cell with a protein, wherein said protein is a lipidated protein; and

contacting said cell with an IgG, comprised of a domain having affinity for said protein. The protein is palmitated protein A and is lipidated with a C16 lipid. The Examiner is interpreting the reference, as related to the claims as follows: the palmitated protein A of the reference reads on the first protein of the instant application. The IgG reads on the second protein of the instant application.

Kim and Peacock do not teach that the second protein being a fusion protein.

However, Brunschwig (see abstract) does teach a fusion protein comprised of B7-1:decay-accelerating factor (DAF) modified with glycosylphosphatidylinositol (GPI). The fusion protein attaches to the cell via GPI. The fusion protein attaches to the cell via GPI> The examiner is interpreting the fusion protein of Brunschwig to read on the second protein. These fusion proteins have a second domain which encodes for a co-stimulator function of costimulators including B7-1 and B7-2. The use of any known co-stimulator is within the purview of one skilled in the art (Applicants admit they are known, page 6 of the specification.)

Since both references are discussing incorporating proteins (either the fusion protein of Brunschwig or the IgG of Kim and Peacock) into cells and the difference between the two references is the method of attachment, the Examiner considers these to be equivalent. Therefore, it is within the purview of one of ordinary skill in the art to that the claimed cell would be produced using either attachment mechanism.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of Kim and Peacock and Brunschwig. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because the method presented by Kim and Peacock is broadly applicable to many studies where it is desired to produce cells with target specific molecules in order to induce specific intercellular interactions.

Applicants are reminded that the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

Art Unit: 1642

308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A handwritten signature in black ink, appearing to read 'Alana M. Harris', with a stylized flourish at the end.

Alana M. Harris, Ph.D.
August 1, 2003